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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,221	11/17/2003	Jonathan J. Langberg	MITRAL.001C2	5022

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EDWARDS LIFESCIENCES CORPORATION  
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EXAMINER
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CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/715,221

Applicant(s)

LANGBERG ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) 25,35,39,41 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24,26-34,36-38,40,42 and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/20/04; 4/10/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group II, Species 1B in the reply filed on January 10, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The reply filed on January 10, 2006 is incomplete for failing to provide applicant's election under Species 2 for the lock, Species 3 for the movement of the apparatus from implantation to remodeling configuration, and Species 4 for the anchor. In a telephone conversation with Mr. David L. Hauser on January 31, 2006, an election was made of Species 2B, Species 3A, and Species 4B. Claims 25, 35, 39, 41 and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

### ***Response to Amendment***

3. The amendment filed January 10, 2006 has been entered. Claims 1-23 and 47-49 have been canceled. Claims 24-46 are currently pending, of which claims 25, 35, 39, 41 and 43 are withdrawn. The claims being considered for further examination on the merits are claims 24, 26-34, 36-38, 40, 42 and 44-46.

***Information Disclosure Statement***

4. The Information Disclosure Statements filed May 20, 2004 and April 10, 2005 have been entered. The references cited therein have been considered by the examiner. An initialed and signed copy of each IDS is enclosed.

***Drawings***

5. The drawings are objected to because it is unclear what "114" in Figure 5 is referring to. In paragraph [0063], "114" has been used to indicate "body 114" of lock 70, as shown in Figures 7-9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

*Specification*

6. The disclosure is objected to because of the following informalities: paragraph [0001] must be updated to indicate that 09/968,272 is now U.S. Patent No. 6,709,456. Appropriate correction is required.

*Claim Objections*

7. Claim 45 is objected to because of the following informalities: on line 2, "10 mm" should be changed to --10 mm<sup>2</sup>--, according to line 9 of paragraph [0067]. Appropriate correction is required.

*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 24, 26-33, 37, 38, 40, 42 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. (USPN 6,210,432, as cited in applicant's IDS) in view of Machek et al. (USPN 5,954,761).

Solem et al. disclose a medical apparatus for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 24, but are silent to an electrode carried by the body. See Figures 12 and 13 and columns 4-5, lines 56-4 for an elongate body (8") movable between a first configuration for transluminal delivery to at least a portion of the coronary sinus

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(5) and a second configuration for remodeling a mitral valve annulus (6) from within the coronary sinus (5). A forming element (26 or 27) is attached to the elongate body (8'') for manipulating the elongate body (8'') between the first transluminal configuration and the second remodeling configuration. Machek et al. teach a lead assembly (10) comprising two expandable, electrode stents (40a, 40b) coupled to conductors (38) that reside in a lead (11), wherein the stents (40a, 40b) anchor the distal end (14) of the lead assembly (10) within the coronary sinus (22) and supply electrical impulses carried by the conductors (38) to the tissue for pacing and sensing. See Figure 2, 3, 4 and 7, column 3, lines 49-50, column 4, lines 35-39 and 53-62, and column 7, lines 2-6. The stent structure (23, 24, 25) in Figure 13 of Solem et al. and the stent structure (40a, 40b) in Figure 7 of Machek et al., are similar in that they are both cylindrical, expandable and appear to be of a mesh. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Machek et al. to include the lead assembly to the apparatus of Solem et al. by making the stents (23, 24, 25) into electrode stents by coupling them to conductors within a lead in a lead assembly in order for the stents to be used for sensing and pacing in addition to anchoring within the coronary sinus.

Claim 26, see Figure 13 for the cylindrical stent of Solem et al., when modified to be an electrode stent, comprising an annular band.

Claim 27-30, see Figures 1, 3 and 4, column 3, lines 35-38 and 62-66 and column 4, lines 53-56 of Machek et al. for at least one electrical conductor (38). A pacing source/cardiac rhythm management device/diagnostic instrument (13; pacemaker, cardioverter/defibrillator, cardiac stimulator) is in electrical communication with the electrical conductor (38).

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Claim 31, see Figures 12 and 13 and columns 4-5, lines 62-4 for the forming element (26 or 27) being secured to the elongate body (8") at a point of attachment and the forming element (26 or 27) being movable relative to the elongate body (8") in order to adjust the elongate body (8") within the coronary sinus (5) between the first and second configurations.

Claim 32, see Figure 13 for the elongate body (8") defining an arc when in the remodeling configuration.

With respect to claims 33, 44 and 45, see Figures 12 and 13. The best fit constant radius curve of the arc, the axial length of the apparatus and the maximum cross sectional diameter through the apparatus will all depend on the geometry of the coronary sinus of the patient into which the apparatus is being implanted, for which a properly sized apparatus will be chosen. Because the apparatus of application and the apparatus of Solem et al. are both being used in the coronary sinus, it is obvious that the apparatus of Solem et al. will have the dimensions required by these claims.

Claim 37, see column 5, lines 14-17 for a coating on the body (8").

Claim 38, see Figures 12 and 13 and columns 4-5, lines 62-4 for the apparatus being movable from the implantation configuration to the remodeling configuration in response to proximal retraction of the forming element (26 or 27).

Claims 40 and 42, see Figure 13 for an anchor (23, 24, 25) for retaining the apparatus at a deployment site within the vessel, wherein the mesh-like structure of the anchor provides a friction enhancing surface for engaging the wall of the vessel, as opposed to a continuous, smooth surface, for example.

Claim 46, see Figures 12 and 13 for the stent (23 or 24) providing as an axially extending support in the body (8”) and attached to the forming element (26 or 27).

### *Double Patenting*

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 24, 26-34, 36-38, 40, 42 and 44-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 6, 14, 17, 18, 20, 22, 24-26 and 30-32 of U.S. Patent No. 6,402,781 in view of Machek et al. The patent claims a medical apparatus for remodeling a mitral valve apparatus with all the elements of claim 24 but is silent to an electrode carried by the body. Machek et al. teach a lead assembly (10) comprising two expandable, electrode stents (40a, 40b) coupled to conductors (38) that reside in a lead (11), wherein the stents (40a, 40b) anchor the distal end (14) of the lead assembly (10) within the coronary sinus (22) and supply electrical impulses carried by the conductors (38) to the tissue for



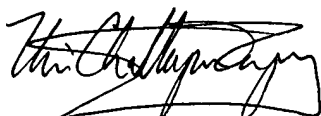
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pacing and sensing. See Figure 2, 3, 4 and 7, column 3, lines 49-50, column 4, lines 35-39 and 53-62, and column 7, lines 2-6. The stent structure (23, 24, 25) in Figure 13 of Solem et al. and the stent structure (40a, 40b) in Figure 7 of Machek et al., are similar in that they are both cylindrical, expandable and appear to be of a mesh. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Machek et al. to include the lead assembly to the apparatus of Solem et al. by making the stents (23, 24, 25) into electrode stents by coupling them to conductors within a lead in a lead assembly in order for the stents to be used for sensing and pacing in addition to anchoring within the coronary sinus.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Urmi Chattopadhyay

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David J. Isabella  
Primary Examiner